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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP., and ISIS PHARMACEUTICALS, INC.

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF

MERCK'S BENCH BRIEF ON GILEAD'S LATE CHALLENGE TO THE ROYALTY BASE

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Defendants (collectively, "Merck") respectfully submit this memorandum of law seeking to preclude plaintiff Gilead from arguing that Gilead and Pharmasset's contribution to the prodrug component of sofosbuvir should reduce the royalty base as well as the royalty rate.[1]

INTRODUCTION

At the charge conference last Friday, it appeared for the first time that Gilead intends to argue that Gilead and Pharmasset's contributions to the prodrug component of sofosbuvir should reduce the damages royalty *base* in addition to the royalty *rate*. This theory, like Gilead's lump sum theory, is nowhere in Gilead's disclosures, and Merck would be prejudiced if Gilead is permitted to pursue it. *See generally* ECF No. 316. Gilead's new argument is also wrong under the law. Clear Federal Circuit precedent teaches that Gilead and Pharmasset's contribution to sofosbuvir should be accounted for in the royalty *rate* and not the base. *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1337-40 (Fed. Cir. 2015).

FACTUAL BACKGROUND

On April 4, 2015, Merck propounded Interrogatory 19 on Gilead requesting, in part:

> (i) Gilead's contention regarding damages owed for such infringement, including the amount and basis for calculating damages (e.g., lost profits, reasonable royalty, price erosion, or any other basis); (ii) the factual basis supporting Gilead's contention, including how Gilead calculated such damages.

Gilead's May 7, 2015 answer to Interrogatory 19 stated, in relevant part,

> "Gilead further objects to this Interrogatory as premature to the extent it calls for information that is properly disclosed during expert discovery, and Gilead will disclose information according to the schedule entered by the Court."

Gilead never supplemented its response to Merck's Interrogatory 19.

Merck's expert, Mr. Carter, set forth in his report a calculation of the royalty base that accounted for all sales of Sovaldi® and Harvoni® less certain adjustments for costs and for the presence of a second active ingredient in Harvoni®. Gilead's damages expert, Dr. O'Brien, did not set forth any opinion with regard to the royalty base used by Mr. Carter. Instead he stated: "Mr. Carter does not properly apportion the contribution of the Patents-in-Suit versus the contributions of the Gilead and Pharmasset in the success of Sovaldi and Harvoni. I will discuss this issue generally *and then apply the apportionment*

[1] Merck has filed a separate brief addressing Gilead's intention to cross-examine Merck's damages expert, Mr. Carter, on the expert report he submitted in the Idenix litigation.

adjustments to Mr. Carter's 10% rate." O'Brien Expert Report, Ex. 1, at ¶ 161 (emphasis added). Dr. O'Brien correctly recognizes that this factor is relevant to the rate, not the base. And Gilead has never identified an alternative dollar amount or basis for calculating the royalty base. At the March 18, 2016, charging conference, Gilead appeared to take the position, for the first time, that its and Pharmasset's contributions in developing the prodrug component of sofosbuvir should reduce the royalty base. When counsel met and conferred on the issue yesterday, counsel for Gilead was unable to assure counsel for Merck that Gilead would not offer this theory during trial.

ARGUMENT

I. GILEAD'S NEW CHALLENGE TO THE ROYALTY BASE SHOULD BE REJECTED FOR THE SAME REASONS AS ITS LUMP-SUM DAMAGES THEORY

As explained thoroughly in Merck's last brief, ECF No. 316, Gilead should not be permitted to raise new arguments about damages that were not disclosed to Merck in response to its contention interrogatory on damages. Merck's Interrogatory 19 requested (1) Gilead's damages theory; (2) any factual basis supporting such a contention; and (3) how Gilead calculated said damages. Gilead's only response was that the interrogatory was premature and information related to damages would be properly disclosed during expert discovery. By choosing to rely solely on its expert report for disclosure of its damages theory, Gilead limited itself to the arguments presented therein. *See Apple, Inc. v. Samsung Electronics Co., Ltd*,. 2013 WL 6001902 (N.D. Cal. 2013); *Radware, Ltd. v. F5 Networks, Inc.*, Case No. 5:13-cv-02024-RMW (N.D. Cal. March 10, 2016).

It would be highly prejudicial to allow Gilead to assert such a challenge when Merck has had no opportunity to explore Gilead's contention through fact or expert discovery. Merck has no idea what royalty base Gilead intends to argue to the jury or the basis for it. This Court should preclude Gilead's new challenge to the royalty base for the same reasons it precluded Gilead's new lump-sum theory.

II. GILEAD'S NEW CHALLENGE TO THE ROYALTY BASE IS MERITLESS.

Even if this Court were inclined to excuse Gilead's failure to disclose its challenge to the royalty base during discovery—which it should not do—Gilead's challenge should be rejected on its merits. There is no question that the royalty base here should be sales of Sovaldi® and Harvoni® (as adjusted to remove the value of the second drug in Harvoni®—an adjustment Gilead acknowledges it is not

challenging). The nucleoside portion and the prodrug portion of sofosbuvir are not separately saleable units; the two are parts of a single compound and are necessarily sold together. Thus, there is no basis for using anything less than the total adjusted sales as a royalty base. Any issue about Gilead and Pharmasset's relative contributions to these products should go to the rate, not the base, of the royalty. This is already set forth in the *Georgia-Pacific* factors, one of which is "[t]he portion of the realizable profits that should be credited to the invention as distinguished from nonpatented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer."

Moreover, recent Federal Circuit precedent is clear that the royalty base for a product that cannot be separated into components—like sofosbuvir—should be total product sales even if the patent only covered some aspects of the product. In *AstraZeneca AB v. Apotex Corp.*, 782 F.3d at 1338, the patents were directed to the improved formulation of a pharmaceutical. Even though the active ingredient was no longer patented, the Federal Circuit found that the proper royalty base was the total sales of the product. *Id.* The court noted specifically that "the standard *Georgia-Pacific* reasonable royalty analysis takes account of the importance of the inventive contribution in determining the royalty rate that would have emerged from the hypothetical negotiation," obviating any need to account for relative contributions to the accused products by reducing the royalty base. *Id.* at 1338. The facts of this case are even more conducive to the use of total product sales as a royalty base because the patents are directed to the active ingredient itself—which is why Gilead never challenged the royalty base in the first place.

III. MR. CARTER'S IDENIX REPORT IS IRRELEVANT TO THIS QUESTION.

Nothing about Mr. Carter's report in the *Idenix* case impacts this question. In both cases, Mr. Carter opined that the appropriate royalty base is the total sales of the product because in both cases the patents cover the drug. That is precisely what the Federal Circuit held in *AstraZeneca*. Mr. Carter's *Idenix* report is simply immaterial to the question of whether Gilead can argue, at the 11th hour, that its contribution to the prodrug reduces both the base and the rate—an improper double-counting.

Dated: March 20, 2016

WILLIAMS & CONNOLLY LLP

By: */s/ Jessamyn S. Berniker*
Jessamyn S. Berniker

Attorneys for Defendants

CERTIFICATE OF SERVICE

I certify that all counsel of record were served on March 20, 2016 with a copy of this document via the Court's CM/ECF system.

/s/ Jessamyn S. Berniker

JESSAMYN S. BERNIKER